

SENATE/HOUSE FILE _____
BY (PROPOSED BOARD OF PHARMACY
BILL)

A BILL FOR

1 An Act making changes to the controlled substance schedules,
2 modifying the regulation of precursor substances, and
3 providing penalties, and including effective date
4 provisions.
5 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

DIVISION I

CONTROLLED SUBSTANCES

Section 1. Section 124.204, subsection 2, Code 2017, is amended by adding the following new paragraph:

NEW PARAGRAPH. *bd.* AH-7921 (3,4-dichloro-N-[(1-dimethylamino) cyclohexylmethyl]benzamide.

Sec. 2. Section 124.204, subsection 9, Code 2017, is amended by adding the following new paragraphs:

NEW PARAGRAPH. *p.* N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-2-carboxamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers. Other names: Furanyl fentanyl.

NEW PARAGRAPH. *q.* N-(1-phenethylpiperidin-4-yl)-N-phenylbutyramide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers. Other names: Butyryl fentanyl.

NEW PARAGRAPH. *r.* N-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-N-phenylpropionamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers. Other names: beta-hydroxythiofentanyl.

NEW PARAGRAPH. *s.* 3,4-Dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methylbenzamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers. Other names: U-47700.

Sec. 3. Section 124.206, subsection 2, paragraph a, unnumbered paragraph 1, Code 2017, is amended to read as follows:

Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, naloxegol, naloxone, and naltrexone, and their respective salts, but including the following:

Sec. 4. Section 124.206, subsection 2, paragraph d, Code 2017, is amended to read as follows:

d. Coca leaves and any salt, compound, derivative, or preparation of coca leaves. ~~Decocainized coca leaves or~~

1 ~~extractions of coca leaves, which extractions do not contain~~
 2 ~~cocaine or ecgonine, are excluded from this paragraph. The~~
 3 ~~following substances and their salts, optical and geometric~~
 4 ~~isomers, derivatives, and salts of derivatives and optical~~
 5 ~~and geometric isomers including cocaine and ecgonine and~~
 6 ~~their salts, isomers, derivatives and salts of isomers and~~
 7 ~~derivatives, and any salt, compound, derivative, or preparation~~
 8 thereof that is chemically equivalent or identical to any of
 9 such substances, are included in this paragraph except that the
 10 substances shall not include:

11 (1) Cocaine Decocainized coca leaves or extractions of coca
 12 leaves, which extractions do not contain cocaine or ecgonine.

13 (2) Ecgonine [123]ioflupane.

14 Sec. 5. Section 124.206, subsection 3, Code 2017, is amended
 15 by adding the following new paragraph:

16 NEW PARAGRAPH. *ac.* Thiafentanil.

17 Sec. 6. Section 124.208, subsection 5, paragraph a,
 18 subparagraphs (3) and (4), Code 2017, are amended by striking
 19 the subparagraphs.

20 Sec. 7. Section 124.210, subsection 2, Code 2017, is amended
 21 by adding the following new paragraph:

22 NEW PARAGRAPH. *c.* 2-[(dimethylamino)methyl]-1-
 23 (3-methoxyphenyl)cyclohexanol, its salts, optical and geometric
 24 isomers and salts of these isomers (including tramadol).

25 Sec. 8. Section 124.210, subsection 3, Code 2017, is amended
 26 by adding the following new paragraphs:

27 NEW PARAGRAPH. *bb.* Alfaxalone.

28 NEW PARAGRAPH. *bc.* Suvorexant.

29 Sec. 9. Section 124.210, subsection 7, Code 2017, is amended
 30 by adding the following new paragraph:

31 NEW PARAGRAPH. *c.* Eluxadoline (5-[[[(2S)-2-amino-3-
 32 [4-aminocarbonyl)-2,6-dimethylphenyl]-1-oxopropyl][(1S)-1-
 33 (4-phenyl-1H-imidazol-2-yl)ethyl]amino]methyl]-2-
 34 methoxybenzoic acid) (including its optical isomers) and its
 35 salts, isomers, and salts of isomers.

1 Sec. 10. Section 124.212, subsection 5, Code 2017, is
2 amended by adding the following new paragraph:

3 NEW PARAGRAPH. *d.* Brivaracetam ((2S)-2-[(4R)-2-oxo-4-
4 propylpyrrolidin-1-yl] butanamide), including its salts. Other
5 names: BRV, UCB-34714, Briviact.

DIVISION II

CODE CHAPTER 124B (PRECURSOR SUBSTANCES) REPEAL

8 Sec. 11. Section 124.401, subsection 5, unnumbered
9 paragraph 1, Code 2017, is amended to read as follows:

10 It is unlawful for any person knowingly or intentionally
11 to possess a controlled substance unless such substance was
12 obtained directly from, or pursuant to, a valid prescription
13 or order of a practitioner while acting in the course of the
14 practitioner's professional practice, or except as otherwise
15 authorized by this chapter. Any person who violates this
16 subsection is guilty of a serious misdemeanor for a first
17 offense. A person who commits a violation of this subsection
18 and who has previously been convicted of violating this chapter
19 or chapter 124A, ~~124B~~, or 453B, or chapter 124B as it existed
20 prior to the effective date of this Act, is guilty of an
21 aggravated misdemeanor. A person who commits a violation of
22 this subsection and has previously been convicted two or more
23 times of violating this chapter or chapter 124A, ~~124B~~, or 453B,
24 or chapter 124B as it existed prior to the effective date of
25 this Act, is guilty of a class "D" felony.

26 Sec. 12. Section 155A.6, subsection 3, Code 2017, is amended
27 to read as follows:

3. The board shall establish standards for pharmacist-intern registration and may deny, suspend, or revoke a pharmacist-intern registration for failure to meet the standards or for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs, or for any violation of this chapter or chapter 124, 124A, ~~124B~~, 126, 147, or 205, or any rule of the board.

1 Sec. 13. Section 155A.6A, subsection 5, Code 2017, is
2 amended to read as follows:

3 5. The board may deny, suspend, or revoke the registration
4 of, or otherwise discipline, a registered pharmacy technician
5 for any violation of the laws of this state, another state, or
6 the United States relating to prescription drugs, controlled
7 substances, or nonprescription drugs, or for any violation of
8 this chapter or chapter 124, 124A, ~~124B~~, 126, 147, 205, or
9 272C, or any rule of the board.

10 Sec. 14. Section 155A.6B, subsection 5, Code 2017, is
11 amended to read as follows:

12 5. The board may deny, suspend, or revoke the registration
13 of a pharmacy support person or otherwise discipline the
14 pharmacy support person for any violation of the laws of
15 this state, another state, or the United States relating to
16 prescription drugs, controlled substances, or nonprescription
17 drugs, or for any violation of this chapter or chapter 124,
18 124A, ~~124B~~, 126, 147, 205, or 272C, or any rule of the board.

19 Sec. 15. Section 155A.13A, subsection 5, paragraph d, Code
20 2017, is amended to read as follows:

21 d. Any violation of this chapter or chapter 124, 124A, ~~124B~~,
22 126, or 205, or rule of the board.

23 Sec. 16. Section 155A.13C, subsection 5, paragraph d, Code
24 2017, is amended to read as follows:

25 d. Any violation of this chapter or chapter 124, 124A, ~~124B~~,
26 126, or 205, or rule of the board.

27 Sec. 17. Section 155A.17, subsection 2, Code 2017, is
28 amended to read as follows:

29 2. The board shall establish standards for drug wholesaler
30 licensure and may define specific types of wholesaler licenses.
31 The board may deny, suspend, or revoke a drug wholesale license
32 for failure to meet the applicable standards or for a violation
33 of the laws of this state, another state, or the United
34 States relating to prescription drugs, devices, or controlled
35 substances, or for a violation of this chapter, chapter 124,

1 124A, ~~124B~~, 126, or 205, or a rule of the board.

2 Sec. 18. Section 155A.42, subsection 4, Code 2017, is
3 amended to read as follows:

4 4. The board may deny, suspend, or revoke a limited drug and
5 device distributor's license for failure to meet the applicable
6 standards or for a violation of the laws of this state, another
7 state, or the United States relating to prescription drugs or
8 controlled substances, or for a violation of this chapter,
9 chapter 124, 124A, ~~124B~~, 126, 205, or 272C, or a rule of the
10 board.

11 Sec. 19. REPEAL. Chapter 124B, Code 2017, is repealed.

12 DIVISION III

13 EFFECTIVE DATE

14 Sec. 20. EFFECTIVE UPON ENACTMENT. This Act, being deemed
15 of immediate importance, takes effect upon enactment.

16 EXPLANATION

17 The inclusion of this explanation does not constitute agreement with
18 the explanation's substance by the members of the general assembly.

19 This bill makes changes to the controlled substance
20 schedules and modifies the regulation of precursor substances.

21 DIVISION I — CONTROLLED SUBSTANCES. The bill classifies
22 four synthetic opioids as schedule I controlled substances in
23 conformance with scheduling actions taken by the United States
24 department of justice, drug enforcement administration. The
25 bill also classifies as a schedule I controlled substance a
26 micro-opioid receptor agonist with analgesic activity similar
27 to morphine.

28 The bill classifies thiafentanil, an opioid and analogue of
29 fentanyl, as a schedule II controlled substance.

30 The bill removes hydrocodone-combination products from
31 the list of substances classified as schedule III controlled
32 substances. Currently, hydrocodone, as a single-entity
33 substance, is classified as a schedule II controlled
34 substance. The change under the bill effectively makes all
35 hydrocodone-containing products subject to the controls,

1 security, reporting, and penalty provisions for schedule II
2 controlled substances.

3 The bill removes naloxegol, a new molecular entity and
4 derivative of naloxone, from control as a schedule III
5 controlled substance. The federal food and drug administration
6 approved naloxegol for the treatment of opioid-induced
7 constipation in adults with chronic non-cancer pain.

8 The bill also removes [\123\I]ioflupane from control as
9 a schedule II controlled substance. This substance is a new
10 molecular entity and is the active pharmaceutical ingredient
11 in the drug DaTscan, approved by the federal food and drug
12 administration for use in diagnosis of patients suspected of
13 having Parkinson's disease.

14 The bill classifies the substance commonly known as
15 tramadol, a centrally acting opioid analgesic, as a schedule
16 IV controlled substance. This substance was previously
17 marketed and distributed as a noncontrolled prescription
18 drug. Effective August 18, 2014, the federal drug enforcement
19 administration classified tramadol as a schedule IV controlled
20 substance under federal law.

21 The bill classifies alfaxalone, a neurosteroid with central
22 nervous system depressant properties, as a schedule IV
23 controlled substance. The federal food and drug administration
24 approved this intravenous injectable anesthetic for use by or
25 on the order of a licensed veterinarian. Alfaxalone is not
26 available by prescription and is approved for use in veterinary
27 practice.

28 The bill classifies suvorexant, an insomnia treatment
29 approved by the federal food and drug administration,
30 as a schedule IV controlled substance. This is a novel,
31 first-in-class, chemical substance and information on actual
32 abuse data is not available. However, data from clinical
33 studies supports the classification in schedule IV.

34 The bill classifies eluxadoline, a new entity with central
35 nervous system opioid properties approved by the federal food

1 and drug administration for the treatment of irritable bowel
2 syndrome with diarrhea, as a schedule IV controlled substance.

3 The bill classifies brivaracetam, also known as briviact
4 or BRV, as a schedule V controlled substance. Briviact is a
5 new molecular entity with central nervous system depressant
6 properties and has been approved as an add-on treatment to
7 other medications to treat partial onset seizures in patients
8 age 16 years and older with epilepsy.

9 It is a class "C" felony pursuant to Code section
10 124.401(1)(c)(8) for any unauthorized person to violate a
11 provision of Code section 124.401 involving a classified
12 substance placed on schedule I, II, or III pursuant to the
13 bill. A class "C" felony for this particular offense is
14 punishable by confinement for no more than 10 years and a fine
15 of at least \$1,000 but not more than \$50,000.

16 It is an aggravated misdemeanor pursuant to Code section
17 124.401(1)(d) for any unauthorized person to violate a
18 provision of Code section 124.401 involving a classified
19 substance placed on schedule IV pursuant to the bill. An
20 aggravated misdemeanor is punishable by confinement for no more
21 than two years and a fine of at least \$625 but not more than
22 \$6,250.

23 If a person possesses a controlled substance in violation of
24 Code section 124.401(5) as a first offense, the person commits
25 a serious misdemeanor. A serious misdemeanor is punishable by
26 confinement for no more than one year and a fine of at least
27 \$315 but not more than \$1,875.

28 DIVISION II — PRECURSOR SUBSTANCES. The bill repeals
29 Code chapter 124B relating to the regulation of precursor
30 substances. Code section 124B.1 defines "precursor substance"
31 to mean a substance which may be used as a precursor in
32 the illegal production of a controlled substance and is
33 specified in Code section 124B.2. Under Code section 124B.2, a
34 manufacturer, retailer, or other person who sells, transfers,
35 or otherwise furnishes to any person in this state a substance

1 listed in Code section 124B.2 is required to file a report with
2 the board of pharmacy unless certain exceptions apply under
3 Code section 124B.6. A person who commits a violation of Code
4 chapter 124B is subject to criminal penalties ranging from a
5 simple misdemeanor to a class "C" felony.

6 DIVISION III — EFFECTIVE DATE. The bill takes effect upon
7 enactment.